

GETTING STARTED WITH COVID-19 POINT OF CARE (POC) ANTIGEN TESTING

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Overview of COVID-19 Point of Care (POC) Antigen Tests

This document provides a step-by-guide to get started with Point of Care (POC) COVID-19 antigen testing. Currently, the Virginia Department of Health (VDH) offers two types of prescription antigen tests:

Abbott BinaxNOW COVID-19 Antigen (Ag) Card – A self-contained antigen test that uses a card and does not require a separate analyzer device. For more information about this product, see <https://www.abbott.com/BinaxNOW-Test-NAVICA-App.html>.

Becton Dickinson (BD) Veritor System – This system uses test devices and a portable analyzer. The analyzer's lifespan is whichever happens first: 3500 test devices are analyzed, OR, the device is used for two years. For more information about this product, see <https://bdveritor.bd.com/en-us>.

Step-by-Step Process for Providers

Step 1: Obtain CLIA Certification

Both the BinaxNOW COVID-19 Antigen Card and the BD Veritor are CLIA-waived tests. Therefore, the facility performing either test needs a current CLIA Certificate of Waiver, CLIA Certificate of Compliance, or a CLIA Certificate of Accreditation. A CLIA certificate must be obtained before BinaxNOW or BD Veritor supplies can be shipped from VDH to the receiving facility.

To obtain a CLIA certificate, fill out the CMS-116 form (see <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS116.pdf>). CMS has a Quick Start Guide located online at <https://www.cms.gov/files/document/cms-clia-laboratory-quick-start-guide-remediated.pdf>.

The CMS-116 requires an original signature; therefore, the completed form must be mailed to:

**Virginia Department of Health
Office of Licensure and Certification
9960 Mayland Drive, Suite 401
Richmond, Virginia 23233**

If you have an existing CLIA certificate, you do NOT need to obtain another one. You will need to notify the VDH Office of Licensure and Certification that the practice/organization will be performing COVID-19 antigen testing. Please email CLIAlab@vdh.virginia.gov with the practice name and CLIA number stating you will be performing COVID-19 antigen testing, and the specific test you will use.

Step 2: Prescriptive Authority Needed for POC Antigen Tests

Abbott BinaxNOW COVID-19 Ag Cards and BD Veritor tests are prescription items; therefore, a medical provider with prescriptive authority must order the test, review the results, and take appropriate medical action, as indicated, for the person tested. If an organization doesn't have, or work with, a medical provider with prescriptive authority, you will need to partner with one.

Step 3: Train Staff/Volunteers to Perform the POC Antigen Test

Both Abbott and Becton Dickinson offer online training for their respective antigen tests. It is important that any training that is done be documented; records need to be kept by the employee and their employer.

Abbott BinaxNOW Training: This can be done online or by a live webinar. If people wish to take both trainings, which is not required, they can. Online training materials are available at <https://www.globalpointofcare.abbott/en/support/product-installation-training/navica-brand/navica-binaxnow-ag-training.html>. For questions about Abbott training or to arrange a live webinar, please contact antigeninfo@vdh.virginia.gov.

BD Veritor Training: BD offers online training and a certificate indicating that the training program has been completed (see <https://bdveritor.bd.com/en-us/education-training>). It's recommended that people trained to use the BD Veritor system print out and keep the certificate of completion for their and the facility's records.

Step 4: Register the facility in the VDH COVID-19 POC Reporting Portal

VDH has established a secure, electronic COVID-19 POC Reporting Portal, which can be found at <https://apps.vdh.virginia.gov/pocreporting/login/login.aspx>. Please register your facility/testing site.

Step 5: Order and Perform Antigen Tests

To order BinaxNOW cards, please complete the following order form: <https://forms.gle/3o1dNSLusNi7w6Sg8>.

To order BD Veritor antigen tests and supplies, submit your request by email to antigeninfo@vdh.virginia.gov.

Step 6: Report COVID-19 Antigen Test Results to VDH

Per the federal CARES Act, all test results (both positive and negative) must be reported to VDH within 24 hours of receipt. This is done by secure electronic reporting through the VDH portal (<https://apps.vdh.virginia.gov/pocreporting/login/login.aspx>).

For 1-page patient handouts about what antigen test results mean and next steps, see the VDH Antigen Testing Results and Next Steps Handout. For forms in languages other than English, see: <https://www.vdh.virginia.gov/coronavirus/resources-and-support/>.

Resources

Guidance Documents

- [VDH Interim COVID-19 Antigen Testing Recommendations](#)
- [VDH Antigen Testing Results and Next Steps Handout](#)
- [Abbott BinaxNOW COVID-19 Antigen Card Training Materials](#)
- [BD Veritor Training Materials](#)
- [VDH Interim COVID-19 Testing Guidance for Healthcare Providers](#)
- [Epidemiology terminology about test performance](#)
- [VDH COVID-19 Molecular and Antigen Testing Algorithms for Healthcare Providers](#)
- [Personal Protective Equipment \(PPE\) Guidance for Rapid Antigen Point of Care Testing](#)

CLIA Certificate Resources

- [How to Obtain a CLIA Certificate of Waiver - Brochure](#)
- [CLIA CMS-116 Form Application for Certification](#)

Templates

- [Antigen Results Letter for LHDs](#)
- [COVID-19 Testing Consent Form - English](#)
- [COVID-19 Testing Consent Form - Spanish](#)
- [COVID-19 Lab Tracker for Testing Facilities](#)
- [COVID-19 Specimen Collection and Rapid Point of Care Testing Standing Order](#)